510(k) Summary

DEC 1 2 2012

for

Kitazato's Cryotop®CL, K112695

1. Submission Sponsor

KITAZATO BioPharma Co., Ltd.
81 Nakajima, Fuji
Shizuoka 416-0907
JAPAN
Phone: +(81) 545-66-2202
Fax: +(81) 545-60-5772
Contact: Futoshi Inoue, President

2. Submission Correspondent

Emergo Group
611 West 5th Street, Third Floor
Austin, TX 78701
Cell Phone: (508) 838.9139
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Richard Vincins, Vice President, QA
Email: project.management@emergogroup.com

3. Date Prepared

7 December 2012

4. Device Name

Trade/Proprietary Name:	Cryotop®CL
Common/Usual Name:	Cryotop Closed
Classification Name:	Assisted Reproduction Labware
Classification Regulation:	884.6160
Classification Panel:	Obstetrics/Gynecology
Product Code:	MQK
Device Class:	II

5. Predicate Devices

Cryo Bio System, HSV Straw, K092398

6. Device Description

CryotopCL is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos.

The CryotopCL device is composed of PET plastic shaft with a fine tip and a straw cap. The fine tip has 5 rounded depressed areas for loading embryos. The CryotopCL device has a "straw" enclosure system for when the unit is placed in the liquid nitrogen. The straw cap is designed to be heat sealed by the user. The protective straw cap has a weighted end to allow proper alignment in the storage container. The CryotopCL device is provided sterile and is for single use only. The device is also provided with a pushing straw to aid in loading the sample holding component of the device into the "straw" enclosure system.

The CryotopCL device conforms to product quality test specifications of our company: appearance, dimension, durability, tensile strength, colorfastness, endotoxin and Mouse Embryo Assay. The sterilization dose of CryotopCL is validated by sterilization validation to maintain the sterility of the device through anticipated storage and handling.

7. Indication for Use

The Cryotop®CL is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos.

8. Technological Characteristics and Substantial Equivalence

The following table compares Kitizato's CryotopCL to the predicate device with respect to intended use, technological characteristics, and principles of operation.

Manufacturer	**KITAZATO BioPharma Co., Ltd.**	**Cryo Bio System**
Trade Name	Cryotop®CL	HSV Straw
510(k) Number	K112695	K092398
Product Code	MQK	MQK
Regulation Number	884.6160	884.6160
Regulation Name	Assisted Reproduction Labware	Assisted Reproduction Labware
Indications for Use:	The CryotopCL is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos.	The HSV Straw is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos.
Overall Design	The device consists of a three piece assembly comprised of the main part containing the fine tip, the protective "straw," and pushing tool to assist in the proper placement of the main part. The straw is designed to be sealed.	The device consists of 3 parts: a resin straw, a capillary tube with a pre-formed gutter attached to a colored handling rod, and a plastic pushing tool to assist in the proper placement of the capillary tube. The straw is designed to be

Manufacturer	KITAZATO BioPharma Co., Ltd.	Cryo Bio System
Trade Name	Cryotop®CL	HSV Straw
	The straw is weighted to allow proper alignment in the storage container. The CryotopCL device is packaged in a single peel off blister pack that is terminally sterilized; 10 (ten) units are placed in a secondary paper pouch for storage purposes.	sealed. The HSV Straw is packaged in a peel off blister pack.
Method of Action	Vitrification Method	Vitrification Method
Sterile	Radiation	Radiation
Cooling Rate	3,000°C/min	2,900°C/min
Rewarming Rate	40,000°C/min	25,000°C/min
Material Composition	PET, Polypropylene	Medical Grade Styrene-Butadiene Copolymer
Contact with Warming Medium	The tip (film) and the shaft of CryotopCL are taken out from straw. Directly immerse the tip (film) into warming medium.	The curved spatula, containing the cryopreserved embryo, is immersed in warming medium where thawing and dilution in the warming medium occur simultaneously.
Performance Testing of Device	Passed	Passed
Mouse Embryo Test Passed	≥80% of 1-cell control embryos	≥80% of 1-cell control embryos
Endotoxin Testing	≤0.5 EU/device	≤0.5 EU/device
Sterility Validation Passed	No microbial growth, SAL 10^{-6}	No microbial growth, SAL 10^{-6}

9. Non-Clinical Testing

The CryotopCL device has undergone cooling/warming rate testing, mechanical testing, dimensional testing, sterility testing, mouse embryo assay testing, and endotoxin testing. Results support that all the specifications have met the acceptance criteria for the device.

- Cooling Rate Testing: Cooling rate of 3,000 °C/min passed
- Warming Rate Testing: Warming rate of 40,000 °C/min passed
- Dimensional Testing: Passes outer diameter, length, width of shaft, and spacing of the embryo holding locations according to specifications
- Mechanical Tensile Testing: Tensile strength to withstand 5N
- Endotoxin Testing: Endotoxin values conform to the value ≤0.5 EU/device
- Sterility Testing: No microbial growth from sterility testing
- Mouse Embryo Assay: ≥80% of 1-cell control embryos develop at 96 hours

The CryotopCL device passed all testing and supports the claims of substantial equivalence.

The CryotopCL device complies with the applicable voluntary standards for sterilization. The device passed all the testing in accordance with national and international standards.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate devices. The substantial equivalence of the device is supported by the non-clinical testing. The validation testing of sterility testing and mouse embryo testing was found to acceptable and supports the claims of substantial equivalence.

11. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the CryotopCL device and the predicate devices do not raise any new types of questions regarding its safety and effectiveness. Kitazato's Cryotop®CL, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 12, 2012

KITAZATO BioPharma Co., Ltd.
% Mr. Richard Vincins, CQA, CBA, RAC (US, EU)
Vice President, Quality Assurance
Emergo Group
611 West 5th Street, Third Floor
AUSTIN TX 78701

Re: K112695
Trade/Device Name: Cryotop®CL
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: November 21, 2012
Received: November 23, 2012

Dear Mr. Vincins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510(k) Number (if known): K112695

Device Name: Cryotop®CL

Indications for Use:

The Cryotop®CL is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2012.12.12 11:10:49 -05'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112695